

Appl. No. : 09/989,995  
Filed : November 21, 2001

### REMARKS

The November 2, 2004, Office Action was based on pending Claims 1-29. The Examiner rejected Claims 1-29. This amendment amends Claims 1-27 and 29, cancels Claim 28, and adds new Claims 30-32. Thus, after entry of this amendment, Claims 1-27 and 28-32 are pending and presented for further consideration.

Reconsideration of the pending claims as amended is therefore respectfully requested.

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Submitted concurrently herewith is a Supplemental Information Disclosure Statement and form PTO-1449 equivalent citing four new references, which recently came to Applicant's attention.

### REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 1-3 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,792,074 to Erbel ("Erbel") in view of U.S. Patent No. 5,402,785 to Leigh et al. ("Leigh"). The Examiner rejected Claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Erbel in view of Leigh and further in view of U.S. Patent No. 6,249,692 to Cowin ("Cowin"). In view of the following discussion and the amendments to Claim 1 *supra*, Applicant respectfully traverses this rejection.

#### Claim 1

Erbel discloses a method of using two infrared cameras and a CT scanner in combination with a calibration phantom and positional markings to update a radiotherapy plan to save time and to improve targeting of a high-energy radiotherapy beam. Erbel's phantom is a structure with markings that can be seen by both the infrared cameras and on CT images. Erbel uses the markings on the calibration phantom to develop a spatial relationship such that the cameras can be used with the radiotherapy machine to localize the high-energy beam on repeat sessions. (See column 4 lines 29-54.)

Thus, Erbel teaches measuring position, not CT x-ray attenuation. Erbel does not disclose, either alone or in combination with the other elements of amended Claim 1, determining a CT attenuation measure of at least one region of a phantom and determining a CT attenuation measure of a region representing blood or heart tissue.

Leigh discloses a method using Magnetic Resonance Imaging (MRI) for measuring the perfusion of moving blood in a subject's body. The blood is magnetically labeled at a labeling position between the heart and a target organ in order to measure the flow of the blood through the organ. (Column 3, lines 19-55.) Leigh does not disclose determining a CT attenuation measure of a phantom or a CT attenuation measure of a region representing blood or heart tissue. The Leigh method measures flow and does not calibrate an image based on CT attenuation.

In contrast, amended Claim 1 recites a method of determining tissue densities from computed tomography (CT) images, comprising acquiring at least one CT image of the subject's body and a calibration phantom; determining a CT attenuation measure of at least one region of the phantom; locating a region of the image representing the subject's blood or heart tissue; determining a CT attenuation measure of the region representing blood or heart tissue; combining the CT measure of the phantom and the CT measure of the blood or heart tissue to develop a calibration relationship; applying the calibration relationship to an image of the subject's body; and recording a calibrated image.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest the limitations of amended Claim 1, Applicant respectfully asserts that Claim 1 is not obvious in view of Erbel and Leigh. Applicant therefore respectfully requests allowance of Claim 1.

#### **Claims 2-5**

Claims 2-5, which depend from Claim 1, are believed to be patentable for the same reasons articulated above with respect to Claim 1, and because of the additional features recited therein.

## REJECTION OF CLAIMS 6-9 UNDER 35 U.S.C. § 103(a)

The Examiner rejected Claims 6 and 9 under 35 U.S.C. § 103(a) as being unpatentable over Erbel in view of U.S. Patent No. 6,052,477 to Wang ("Wang"). The Examiner rejected Claims 7 and 8 under 35 U.S.C. § 103(a) as being unpatentable over Erbel in view of Wang and further in view of U.S. Patent No. 6,687,333 to Carrol ("Carrol"). In view of the following discussion and the amendments to Claim 6 *supra*, Applicant respectfully traverses this rejection.

### Claim 6

Please see the above discussion of Erbel with respect to Claim 1. Erbel does not disclose, among the other elements of amended Claim 6, locating a measurement region in at least one area of the image containing blood, determining a measured CT number representing x-ray attenuation of the region, and determining a reference CT number representing x-ray attenuation of blood. The Erbel method measures position, and does not calibrate or correct images based on CT attenuation.

Wang discloses a technique for localizing externally attached markers. By placing three or more such markers into a patient, a 3-D coordinate system can be established within the patient and spatially associated to the images such that a surgeon can precisely locate specific anatomic structures. The method may enhance the surgeon's ability to perform surgery by allowing a display of a physical position in image space in real-time. (See column 7 lines 24-28.) Wang does not disclose locating a measurement region in at least one area of the image representing blood, determining a measured CT number representing x-ray attenuation of the region, determining a reference CT number representing x-ray attenuation of blood, and correcting the at least one image by a relationship between the reference CT number and the measured CT number of the region.

As with Erbel, the Wang method measures position and does not correct an image based on CT attenuation.

In contrast, amended Claim 6 recites a method to calibrate a computed tomography (CT) density of a tissue, the method comprising acquiring at least one image containing voxels representing x-ray attenuation in the tissue; locating a

measurement region in at least one area of the image representing blood; determining a measured CT number representing x-ray attenuation of the region; determining a reference CT number representing x-ray attenuation of blood; and correcting the at least one image by a relationship between the reference CT number and the measured CT number of the region.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest the limitations of amended Claim 6, Applicant respectfully asserts that Claim 6 is not obvious in view of Erbel and Wang. Applicant therefore respectfully requests allowance of Claim 6.

#### **Claims 7-9**

Claims 7-9, which depend from Claim 6, are believed to be patentable for the same reasons articulated above with respect to Claim 6, and because of the additional features recited therein.

#### **REJECTION OF CLAIMS 10-14 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 10-14 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,490,476 to Townsend et al. ("Townsend") in view of Leigh. In view of the following discussion and the amendments to Claim 10 *supra*, Applicant respectfully traverses this rejection.

#### **Claim 10**

Townsend discloses a combined PET (position emission tomography) and X-ray CT tomographic technique for obtaining CT and PET images sequentially in a single device. Townsend discloses how to align two images to overcome internal organ movement, variations in scanner bed profile, and patient positioning. Townsend does not disclose determining a CT attenuation measure of at least one voxel in the heart or blood region; identifying at least one region that represents calcium in the image; determining a CT attenuation measure of the calcium; and correcting the at least one region that represents calcium using a relationship between the CT attenuation measure of the heart or blood and a reference CT attenuation measure of heart or

blood. Townsend measures position and does not correct an image based on CT attenuation.

Leigh discloses a method using Magnetic Resonance Imaging (MRI) for measuring the perfusion of moving blood in a subject's body. The blood is magnetically labeled at a labeling position between the heart and a target organ in order to measure the flow of the blood through the organ. (Column 3, lines 19-55.) Leigh does not disclose determining a CT attenuation measure of a phantom or a CT attenuation measure of a region representing blood or heart tissue. The Leigh method measures flow and does not correct an image based on CT attenuation.

In contrast, amended Claim 10 recites a method of determining a coronary calcium measure from computed tomography images, the images containing voxels representing x-ray attenuation of a subject's heart, the method comprising acquiring at least one image that includes the heart; identifying a region of the heart or blood in the image; determining a CT attenuation measure of at least one voxel in the heart or blood region; identifying at least one region that represents calcium in the image; determining a CT attenuation measure of the calcium; and correcting the at least one region that represents calcium using a relationship between the CT attenuation measure of the heart or blood and a reference CT attenuation measure of heart or blood.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest the limitations of amended Claim 10, Applicant respectfully asserts that Claim 10 is not obvious in view of Townsend and Leigh. Applicant therefore respectfully requests allowance of Claim 10.

#### **Claims 11-14**

Claims 11-14, which depend from Claim 10, are believed to be patentable for the same reasons articulated above with respect to Claim 10, and because of the additional features recited therein.

**REJECTION OF CLAIMS 15-19 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 15-19 under 35 U.S.C. § 103(a) as being unpatentable over Townsend in view of Wang. In view of the following discussion and the amendments to Claim 15 *supra*, Applicant respectfully traverses this rejection.

**Claim 15**

As discussed above, Townsend discloses a combined PET (position emission tomography) and X-ray CT tomographic technique for obtaining CT and PET images sequentially in a single device. Townsend discloses how to align two images to overcome internal organ movement, variations in scanner bed profile, and patient positioning. Townsend does not disclose determining a CT attenuation measure of at least one voxel in the heart or blood region; identifying at least one region that represents calcium in the image; determining a CT attenuation measure of the calcium; and correcting the at least one region that represents calcium using a relationship between the CT attenuation measure of the heart or blood and a reference CT attenuation measure of heart or blood. Townsend measures position and does not correct an image based on CT attenuation.

Also as discussed above, Wang discloses a technique for localizing externally attached markers. By placing three or more such markers into a patient, a 3-D coordinate system can be established within the patient and spatially associated to the images such that a surgeon can precisely locate specific anatomic structures. The method may enhance the surgeon's ability to perform surgery by allowing a display of a physical position in image space in real-time. (See column 7 lines 24-28.) Wang does not disclose locating a measurement region in at least one area of the image representing blood, determining a measured CT number representing x-ray attenuation of the region, determining a reference CT number representing x-ray attenuation of blood, and correcting the at least one image by a relationship between the reference CT number and the measured CT number of the region. Wang measures position and does not correct an image based on CT attenuation.

In contrast, amended Claim 15 recites a method of calibrating a computed tomography (CT) image based on in vivo tissue density, the method comprising

acquiring a CT image of the subject's body; segmenting a region of the image representing a reference tissue of the subject's body; determining a CT density measure of at least one voxel represented in the reference tissue region; correcting the image based on the CT density measure of the reference tissue; and recording the corrected image.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest the limitations of amended Claim 15, Applicant respectfully asserts that Claim 15 is not obvious in view of Townsend and Wang. Applicant therefore respectfully requests allowance of Claim 15.

#### **Claims 16-19**

Claims 16-19, which depend from Claim 15, are believed to be patentable for the same reasons articulated above with respect to Claim 15, and because of the additional features recited therein.

#### **REJECTION OF CLAIMS 20-24 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claims 20-24 under 35 U.S.C. § 103(a) as being unpatentable over Townsend in view of U.S. Patent No. 6,674,834 to Acharya et al. ("Acharya"). In view of the following discussion and the amendments to Claim 15 *supra*, Applicant respectfully traverses this rejection.

#### **Claim 20**

Please see the above discussion of Townsend with respect to Claims 10 and 15. Townsend measures position and does not calibrate at least one image pixel based on CT attenuation.

Acharya discloses a quality-control phantom for evaluating calcium-scoring systems for accuracy and to compare different imaging systems. Acharya does not disclose, among other elements of amended Claim 20, determining a calibration equation that includes a slope of CT attenuation numbers in the calibration phantom and that includes an intercept determined from the CT attenuation measure of voxels

within the boundaries; correcting pixels within the image by the calibration equation; and identifying voxels above a threshold value to detect calcium within the artery.

In contrast, amended Claim 20 recites a method to quantify calcium in an artery of a human subject represented in a computed tomography (CT) image, the method comprising scanning a reference calibration phantom containing calcium; calibrating at least one image pixel using the calibration phantom; locating boundaries of blood or the heart; determining a CT attenuation measure of voxels within the boundaries; determining a calibration equation that includes a slope of CT attenuation numbers in the calibration phantom and that includes an intercept determined from the CT attenuation measure of voxels within the boundaries; correcting pixels within the image by the calibration equation; and identifying voxels above a threshold value to detect calcium within the artery.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest these limitations of amended Claim 20, Applicant respectfully asserts that Claim 20 is not obvious in view of Townsend and Acharya. Applicant therefore respectfully requests allowance of Claim 20.

#### **Claims 21-24**

Claims 21-24, which depend from Claim 20, are believed to be patentable for the same reasons articulated above with respect to Claim 20, and because of the additional features recited therein.

#### **REJECTION OF CLAIMS 25, and 27-29 UNDER 35 U.S.C. § 102(b)**

The Examiner rejected Claims 25, 27-29 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6, 301,495 to Gueziec et al. ("Gueziec"). In view of the following discussion and the amendments to Claim 15 *supra*, Applicant respectfully traverses this rejection.

#### **Claim 25**

Gueziec discloses intraoperatively providing a surgeon with visual information by simulation for surgical procedures. The method appears to allow the fusion of data and



images to generate simulated data for a 3-D surgical or therapy plan. Gueziec does not disclose, among other elements of amended Claim 25, calibrating an image of a subject by calibrating pixel values of the image based on pixel values of a reference material; defining image display gray ranges of window and level for the calibrated image of the subject; and displaying the gray ranges of window and level in units based on the reference material. Rather, Gueziec calibrates for distances and position, not pixel values.

In contrast, amended Claim 25 recites a method of displaying a calibrated CT image of a subject, the method comprising imaging a subject to produce an image; imaging a reference material having a known property other than x-ray attenuation; calibrating the image of the subject by calibrating pixel values of the image based on pixel values of the reference material; defining image display gray ranges of window and level for the calibrated image of the subject; displaying the gray ranges of window and level in units based on the reference material; and displaying the calibrated images of the subject with the defined display gray ranges.

Because the references cited by the Examiner, either alone or in combination, do not disclose, teach, or suggest these limitations of amended Claim 25, Applicant respectfully asserts that Claim 25 is not anticipated by Gueziec. Applicant therefore respectfully requests allowance of Claim 25.

#### **Claims 27 and 29**

Claims 27 and 29, which depend from Claim 25, are believed to be patentable for the same reasons articulated above with respect to Claim 25, and because of the additional features recited therein.

#### **Claim 28**

Applicant has canceled Claim 28 without prejudice or disclaimer. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejection under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6, 301,495 to Gueziec et al.

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#### **REJECTION OF CLAIM 26 UNDER 35 U.S.C. § 103(a)**

The Examiner rejected Claim 26 under 35 U.S.C. § 103(a) as being unpatentable over Gueziec in view of Acharya. Claim 26, which depends from Claim 25, is believed to be patentable for the same reasons articulated above with respect to Claim 25 over Gueziec. Further, because of the additional features recited therein, Claim 26 is believed to be nonobvious over Gueziec in view of Acharya.

#### **NEW CLAIMS 30-32**

New Claims 30-32 have been added to more fully define the Applicant's invention and are believed to be fully distinguished over the prior art of record.

New Claims 30 and 31 depend from amended Claim 25 and are believed to be allowable for the same reasons articulated above with respect to Claim 25, and because of the additional features recited therein.

New Claim 32 depends from amended Claim 20 and is believed to be allowable for the same reasons articulated above with respect to Claim 20, and because of the additional features recited therein.

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### CONCLUSION

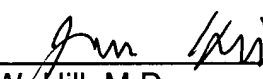
Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. In light of the above remarks and amendments, reconsideration of the claims and withdrawal of the outstanding rejections is specifically requested. If any questions remain, however, the Examiner is cordially invited to contact the undersigned attorney so that any such matters may be promptly resolved.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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